Biotech Daily

Friday May 15, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OSPREY UP 11%; KAZIA DOWN 5%**

*** DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS**

*** CELLMID RESPONDS TO ARTICLE, EXTENDS RESPONSE SUSPENSION**

*** TELIX: PHARMALOGIC TO DISTRIBUTE TLX591-CDX IN THE US**

*** THORNEY, TIGA TAKE 7% OF MICRO-X**

*** GI DYNAMICS RECEIVES $302k US COVID-19 PAYCHECK LOAN**

MARKET REPORT

The Australian stock market was up 1.43 percent on Friday May 15, 2020, with the ASX200 up 76.1 points to 5,404.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded.

Osprey was the best, up 0.1 cents or 11.1 percent to one cent, with 3.95 million shares traded.

Optiscan climbed 7.5 percent; Telix and Uscom improved more than four percent; Dimerix was up 3.9 percent; Antisense and Impedimed rose more than two percent; Compumedics, Next Science, Pro Medicus, Proteomics and Volpara were up one percent; or more; with Clinuvel, Cochlear and CSL up by less than one percent.

Kazia led the falls, down two cents or five percent to 38 cents, with 287,423 shares traded.

Immutep, Imugene, Pharmaxis and Resonance lost more than three percent; Orthocell fell 2.6 percent; Cynata, Genetic Signatures, Medical Developments, Neuren, Opthea, Polynovo and Starpharma were down more than one percent; with Cyclopharm, Mesoblast, Nanosonics and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS

By Tim BOREHAM

ASX Code: TLX

Share price: $1.42

Market cap: $360.2 million

Shares on issue: 253,644,634

Chief executive officer: Dr Chris Behrenbruch

Board: (Harry) Kevin McCann (chairman), Dr Behrenbruch, Dr Andreas Kluge (co-founder), Dr Mark Nelson, Oliver Buck, Jann Skinner

Financials (March quarter): revenue $1.14 million, cash outflows $14.11 million, cash on hand $34.5 million, current quarters of funding: 2.4; **(2019 year):** revenue of $3.48 million (previously $195,000), loss after tax $27.8 million (previously $13.8 million deficit).

Major shareholders: Elk River Holdings (Dr Behrenbruch) 9.74%, Dr Kluge 9.74%, Fidelity International 7.93%.

A mere four years after being formed and two and a half years after listing on the ASX, the developer of oncology imaging devices is on the cusp of commercializing its first product.

As chief business officer Dr David Cade says: "We have made an extraordinary amount of progress in those intervening short years."

(Then again, it helps to IPO with phase II and III trials underway rather than at the lab-bench stage.)

Specifically, the company has just filed a European marketing application for its prostate cancer imaging agent.

A US submission is "almost ready to go" as well.

Meanwhile, Telix's proposed antibody-based imaging product for renal (kidney) cancer is subject to a phase III registration trial.

Beyond that, Telix aspires to develop actual treatments based on its radio immunotherapy or molecularly targeted radiation (MTR).

As an exponent of nuclear medicine, Telix shares some traits with the lung imaging outfit Cyclopharm, which we covered last week.

Telix also has more than passing similarities with Sirtex Medical – the targeted radiation house taken over by China's CDH Investments for a chunky $1.9 billion in 2018.

Inside the Telix machine

Telix was founded in November 2015 by Dr Chris Behrenbruch and Dr Andreas Kluge and incorporated in November 2015.

Dr Kluge founded the Dresden-based radiopharmaceutical outfit Therapeia, which owned the background technology to TLX-101, and Telix acquired Therapeia in October for a nominal cash sum and the assumption of about $1 million of debt.

Dr Behrenbruch is also the executive director of wound-care play Factor Therapeutics, and left Amplia Therapeutics in February having achieved the reformation of the previous Innate Immunotherapeutics – and once was best known for his authorship of the defunct biotech critique, ASX Long Tail.

Dr Cade joined last October, having been chief medical officer at Cochlear. Before that, he held senior roles at Sirtex.

While at Sirtex, Dr Cade took a good look at Telix's assets and tried to convince Sirtex to invest in the company, but the conservative directors demurred.

In one of the biggest life science initial public offers (IPO) since CSL's in 1994, Telix listed in November 2017 after raising $50 million at 65 cents apiece.

(Reva raised $85 million in December 2010 and filed for bankruptcy in January this year. GI Dynamics raised $80 million in August 2011 and, unable to raise funds, is awaiting advice from the ASX about delisting.)

The offer was backed by a cabal of heavyweights including private equity house CVC and former Macquarie Bank chief Allan Moss (Telix chairman Kevin McCann formerly chaired Macquarie, so there's a deep pocket link).

In 2018, Telix exercised a $US10 million ($AUD15.6 million) option to buy French biotech Atlab, which held clinical data and manufacturing intellectual property relevant to the prostate cancer program.

A more targeted approach

A relatively new discipline, molecularly targeted radiation allows radioactive isotopes to be delivered via Telix's patented molecules in a selective way, so that they only reach the tumors in question.

In the most layperson of terms, these agents attach to biological targets expressed by the cancers and that's how the radiation can be delivered without blasting away at healthy cells as well.

Alternatively, molecularly targeted radiation can be used as an enhanced diagnostic tool based on existing hospital imaging equipment. A current problem with imaging is that it uses the unstable gas iodine, which creates "noisy" images and is poor at detecting smaller tumors.

Prostate imaging

Telix's prostate cancer imaging agent is called TLX591-CDx (as in companion diagnostic).

The aforementioned European application is via the Danish Medicines Agency - and let's hope 'our' Crown Princess Mary puts in a good word.

"The use of our technology has also now been written into clinical practice guidelines in Europe and the US, so we expect rapid adoption post-approval," Dr Behrenbruch says.

The Danish submission pertains to imaging of patients with elevated prostate specific antigen (PSA) after radical prostatectomy (prostate removal) or radiation therapy.

Dubbed as "men's breast cancer" because it is so common, prostate cancer is diagnosed in 175,000 patients a year, in the US alone.

Many undergo a prostatectomy and are cured. But about 70,000 of them relapse and require prostate specific antigen (PSA) blood tests.

The trouble is that current diagnostic imaging scans only have enough resolution to detect a one centimetre tumor, by which time it is too late.

Telix's agent enables a positron emission tomography (PET) scan to show a more accurate picture of the biology of the recurrence; and whether repeat surgery or radiation therapy is needed.

In February, Telix received positive feedback from the US Food and Drug Administration, which deemed the current safety and efficacy data to be sufficient.

The key reason for this is, that while unapproved, 11,500 doses have been used for clinical trials or for special access and compassionate use.

"The FDA is very familiar with the drug because it is being used in US clinical trials already," Dr Cade says.

Renal imaging

Known as Zircon, the phase III trial for Telix's renal cancer imaging agent TLX250-CDx is recruiting 252 patients across 26 sites.

After Covid-19 related delays, the Zircon study is expected to be fully up and running again in September.

Depending on the results, the company plans to submit this one as an NDA (new drug application) to the FDA – hooray, hooray.

Zircon is designed to enroll patients scheduled for a partial nephrectomy (that is, the kidney lump is removed by a surgical urologist).

The trial involves the patient being injected with the imaging agent and then undergoing a positron emission tomography (PET) scan, which determines whether the lump is a nasty clear cell renal cell carcinoma or something more benign.

The PET scan is then compared with the surgically removed specimen that comes back in a bottle 10 days later.

“So, we’re looking at the sensitivity and specificity of the imaging test compared with tissue histology, which is the ‘source of truth’,” Dr Cade says.

He says many patients having scans for upper abdominal pain are found to have an asymptomatic kidney mass. But the only way of knowing for sure is with an invasive biopsy (which is painful and risks the needle leaving a trail of cancer cells along the entry route).

“So, there’s a great need to for a non-invasive PET scan to work out what it is with high sensitivity. That’s a diagnostic capability that doesn’t presently exist.”

A prostate treatment?

While less advanced that the imaging product, a prostate cancer therapy would put Telix in a similar category to Sirtex and its SIR-Spheres liver cancer therapy.

Dr Behrenbruch says that apart from commercializing an imaging product, the “big event” for 2020 will be the launch of a phase III trial, called Prostact, for second-line metastatic prostate cancer.

“After a huge amount of work, the team is now ready to engage with the FDA on this program,” he told shareholders at the company’s ‘virtual’ annual general meeting, this week.

“We expect to get a meeting around mid-July, assuming that Covid-19 isn’t pushing out timelines too badly.”

Telix also has a less advanced glioblastoma (brain cancer) program, TLX101-CDx, which has started recruiting 22 patients for a phase I/II study.

Financials and performance

Telix reported revenue of $3.5 million and orders of $4.4 million in calendar 2019, both pertaining to the aforementioned prostate cancer imaging kits.

“Although nascent and hardly indicative of the market opportunities we are pursuing, this revenue is also meaningful because it required the company to develop the framework and infrastructure to deliver a commercial product,” Dr Behrenbruch says.

Telix’s March quarter revenues of $1.14 million were affected by the Covid-19-related slowdown in clinical work.

At the end of March, the company reported cash of just under $35 million, having raised $45 million in a private placement and share purchase plan last August (at $1.30 a share).

Dr Cade says this cash should be enough to last until mid-2021 and support the two imaging product launches.

But a prostate therapy trial would require $70 million to $90 million, probably funded by a capital raising of $100 million or so.

Dr Cade expects the company to undertake the trial itself, rather than take on a partner.

“I don’t think it’s beyond a small Australian life sciences company to do it,” Dr Cade says.

“We will probably steer towards a capital raise and run the trial ourselves with a big [contract research organization] partner.”

He notes the company undertook the renal imaging trial off its own bat.

With prostate imaging, Telix models annual revenues around $US105 million ($166 million).

The kidney imaging market is thought to be one quarter the size of the prostate cancer market.

Meanwhile, Telix shares have traded as low as 48 cents (March 2018) and as high as $1.91 (late November 2019).

“We have accomplished an enormous amount since the last capital raise that is not reflected in the company’s current share price,” Dr Behrenbruch says.

Dr Boreham’s diagnosis:

While the company describes its business as “theranostics” - therapeutics and diagnostics (geddit?) - Dr Behrenbruch says “the largest value inflection points that Telix will achieve over the next two to three years will come from the therapeutics side of the business”.

Ultimately, Telix aspires to become the fourth mega-sized Aussie life sciences outfit, joining CSL, Resmed and Cochlear on the podium of global champions.

“But we don’t want to join companies like Sirtex and Peplin that were sold mid-stage to offshore buyers,” Dr Cade says. “We want jobs for our kids.”

Telix won’t be an overnight success, but we can only agree with Dr Cade’s assertion that 2020 will be a “pivotal year” for the company.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He still struggles with the spelling of ‘prostrate’ and ‘prostate’, but it’s not quite as embarrassing as confusing ‘public’ with ‘pubic’.

CELLMID

Cellmid says it has responded to an article in the Australian Financial Review, but requested and extension to its voluntary suspension on the response.

Last week, Cellmid requested a trading halt “whilst the company considers its response to a media article” and followed it with a request for a voluntary suspension earlier this week (BD: May 7, 11, 2020).

Today the company said the article “contained several incorrect statements” and it had responded in an article on its website.

Cellmid said the article referred to a post-market review by the Australian Therapeutic Goods Administration of the Wondfo Covid19 antibody test (BD: Mar 30, 2020).

The company said the review was a condition for all point-of-care tests listed on the Australian Register of Therapeutic Goods and was “a necessary part of the post market review that all 27 sponsors of these [tests] are subject to, including the two other sponsors of the Wondfo [test]” and was being undertaken by Melbourne’s Peter Doherty Institute.

Cellmid said the review “does not preclude Cellmid from selling its Wondfo Sars-CoV-2 [tests] to healthcare professionals, subject to the TGA’s conditions and other regulatory requirements”.

The company said that during the ASX review of its proposed response to the Financial Review article, it was apparent that the ASX had questions in relation to the review process and other media reports regarding the tests.

Cellmid said that the ASX “expressed their view … that the media articles, whether accurate or not, could lead to a false market in the company’s shares”.

The company said a number of articles did “not correctly reference the intended use of the tests which … Cellmid has previously attempted to clarify through the publication of the article titled ‘Utility of the Wondfo Sars-Cov-2 Antibody test’ on its website”.

Cellmid said it had not received the Doherty Review results for the Wondfo test nor did it have an indication when those results would be received, it had not supplied any Wondfo tests to the Australian Government and it was not aware that any other company had.

Biotech Daily asked the Minister for Health and the Department of Health for details of tests approved or disallowed, and was referred to a series of websites including a Doherty Institute ‘Post-market validation of three serological assays for Covid-19, April 29, 2020’.

The Institute said it reviewed two lateral flow assays Onsite IgM/IgG Rapid Test and the Vivadiag IgM/IgG Rapid Test, and the Euroimmun EIA laboratory-based enzyme immune-assay and “the performance characteristics of both [point-of-care tests] are below that reported by the manufacturer”

“Our observed sensitivities and specificities of the Euroimmun EIA assay are broadly in keeping with the manufacturer’s updated performance criteria … but further highlight the poor sensitivity of serology in acute infection,” the Institute said.

Cellmid last traded at 18.5 cents.

TELIX PHARMACEUTICALS

Telix says it has a US commercial distribution agreement with Pharmalogic Holdings Corp to distribute TLX591-CDx for metastatic prostate cancer.

Telix said that under the agreement, the Boca Raton, Florida-based Pharmalogic would prepare and deliver patient-specific unit-doses of TLX591-CDx through its network of 27 nuclear medicine pharmacies.

The company said that Pharmalogic predominantly serviced regional and rural areas in the Midwest and Northeast of the US.

Telix was up 5.5 cents or four percent to $1.42.

MICRO-X

Melbourne's Thorney Technologies and Tiga Trading say they have increased their shareholding in Micro-X from 8,856,760 shares (6.14%) to 26,282,972 shares (7.36%).
Thorney and Tiga said that on January 2, December 24, 2019 and April 23, 2020 they acquired 10,832,103 shares through placements at 27 cents, 20 cents and 14 cents , respectively, and on May 13, 2020 they acquired 6,594,109 shares through a 1 for 5.6 entitlement offer and sub-underwriting, at 14 cents a share.
Micro-X fell half a cent or 3.6 percent to 13.5 cents.

GI DYNAMICS

GI Dynamics says it has received $US195,147 ($A302,276) from the US Paycheck Protection Program for Covid-19 relief.
GI Dynamics said the loan had an interest rate of 1.0 percent a year, was payable monthly from December 1, 2020 and could be prepaid at any time prior to the maturity date.
The company said that seven weeks after the issue date, it could apply for loan forgiveness if funds were used for qualifying expenses, including the retention of workers, maintenance of payroll and for mortgage, lease and utility payments.
GI Dynamics said it intended to use the entire loan for these qualifying expenses.
GI Dynamics last traded at 0.2 cents.